Baireddy Akhila et al, 2026, Vol.14, No.6: 114-120

International Journal of Chemistry and Pharmaceutical Sciences

https://doi.org/10.30904/j.ijcps.2026.4990 | E-ISSN: 2321-3132

An Investigation into the Differences in Regulatory Approval Pathways for New Drug Applications (NDA) Between the US, EU, and India

Baireddy Akhila*, K Nagasree, P. Laxmi, K Shravan Kumar

Samskruti College of Pharmacy, Kondapur, Ghatkesar, Medchal, Hyderabad-501301, Telangana, India

****Corresponding E-Mail:** principal.y7@gmail.com*

Received: 10-03-2026 | Revised: 08-04-2026 | Accepted: 16-05 2026 | Published: 30-06-2026

Abstract:

This study investigated the differences in regulatory approval pathways for New Drug Applications (NDAs) in the United States, European Union, and India, providing a comparative perspective on their statutory frameworks, dossier requirements, review procedures, expedited programs, exclusivity provisions, post-approval lifecycle management, and strategic implications for sponsors. The US operates under a centralized FDA/CDER-CBER model, the EU under a networked EMA–NCA structure, and India through a hybrid central-plus-state CDSCO/DCGI system under NDCTR 2019. All three regions have adopted the ICH Common Technical Document (CTD), with mandatory eCTD in the US and EU, while India uses SUGAM and is transitioning toward full eCTD integration. Module 1 remains region-specific. US reviews are anchored in PDUFA goals (10 months standard, 6 months priority). EMA's centralized pathway sets a 210-day clock (150 days accelerated), while India aims for ~90 working days under NDCTR, with "deemed approvals" reducing administrative pendency. FDA's Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review; EMA's PRIME, Accelerated Assessment, Conditional MA; and India's accelerated approvals, reliance, and deemed approvals all serve to address unmet medical needs, though with varying obligations. US (5 years NCE, 12 years biologics, 7 years orphan) and EU (8+2+1, 10 years orphan) provide strong protection. India has no standalone data exclusivity, emphasizing access and affordability. US emphasizes structured supplements (PAS/CBE/Annual), REMS, and APQR. EU harmonizes via Type IA/IB/II variations, RMPs, PSURs. India requires PSURs, Phase IV studies, and renewals, gradually strengthening its framework. Filing sequences often follow US → EU → India, but therapeutic area considerations (infectious diseases, oncology) may alter order. Harmonization opportunities include ICH membership, reliance models, and digital transformation. Enhancing regulatory convergence via reliance, digital platforms, harmonized PV obligations, balanced exclusivity, and adaptive approval models can reduce redundancies, promote innovation, and accelerate patient access globally.

Keywords: CDSCO, New Drug Applications, CDSCO, DCGI, India

Introduction

The pharmaceutical industry operates within a highly regulated environment where the approval of new drug applications (NDAs) represents a critical step in ensuring that innovative therapies reach patients safely, effectively, and in a timely manner. Regulatory frameworks serve as the cornerstone of public health protection by establishing rigorous scientific and legal standards for evaluating the quality, safety, and efficacy of medicinal products before they enter the market. While globalization of drug development has accelerated in recent decades, significant regional variations in approval processes persist, influencing the pace of innovation, patient access, and strategic decision-making for pharmaceutical sponsors.

The United States, European Union, and India represent three key regulatory jurisdictions that illustrate both convergence and divergence in drug approval pathways. The U.S. Food and Drug Administration (FDA) operates one of the most established systems, with structured NDA submission routes under the Federal Food, Drug, and Cosmetic Act and performance goals defined by the Prescription Drug User Fee Act (PDUFA). The European Medicines Agency (EMA), functioning within a multi-state governance framework, emphasizes harmonization across member states while offering centralized, decentralized, and mutual-recognition procedures. India, governed by the Central Drugs Standard Control Organization (CDSCO) under the New Drugs and Clinical Trials Rules (NDCTR) 2019, has undergone recent reforms aimed at improving transparency, reducing approval timelines, and aligning with international standards, while still addressing domestic healthcare priorities. Despite their shared reliance on the International Council for Harmonisation's Common Technical Document (ICH-CTD) as a backbone for dossier preparation, the US, EU, and India diverge in several crucial dimensions. These include regulatory timelines, evidentiary requirements, expedited approval mechanisms, clinical trial obligations, data exclusivity protections, and post-approval lifecycle management. For instance, the FDA's expedited programs such as Fast Track, Breakthrough Therapy, and Accelerated Approval provide sponsors with structured opportunities for early engagement and rolling submissions. The EMA offers Conditional Marketing Authorisations, PRIME designation, and accelerated assessments, while India has introduced "deemed approvals" and clinical-trial waivers to encourage innovation and facilitate patient access to critical medicines. Understanding these similarities and differences is not only important for academic inquiry but also essential for multinational pharmaceutical

companies navigating global development strategies. A comparative analysis of the three systems sheds light on how regulatory science interacts with policy, law, and patient needs, ultimately shaping global access to new medicines. It further highlights the challenges of harmonization and the opportunities for cross-learning among regulators in pursuit of efficient, evidence-based, and patient-centered approval processes.

Materials and Methods

Research Design

This study adopts a **comparative qualitative research design**, focusing on analyzing and synthesizing regulatory frameworks governing New Drug Applications (NDAs) in three major jurisdictions: the United States, the European Union, and India. The methodology is based on **document analysis, policy review, and comparative evaluation**, with the objective of identifying similarities, differences, and emerging trends in regulatory approval pathways.

Data Sources: Primary Sources

Official Regulatory Guidelines and Acts:

United States: Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 CFR 314, Prescription Drug User Fee Act (PDUFA) guidance documents, FDA Manuals of Policies and Procedures.

European Union: Regulation (EC) No 726/2004, Directive 2001/83/EC, EMA guidelines on marketing authorisation, Committee for Medicinal Products for Human Use (CHMP) reports. India: Drugs and Cosmetics Act, 1940; New Drugs and Clinical Trials Rules (NDCTR), 2019; CDSCO guidance documents, SUGAM portal notifications.

Secondary Sources

- Published literature including journal articles, textbooks, and reviews on drug regulation, expedited approvals, and harmonization.
- Reports from the **World Health Organization (WHO)**, **International Council for Harmonisation (ICH)**, and regulatory think-tanks.
- Policy analyses and industry white papers on regulatory timelines, data exclusivity, and global drug development strategies.

Data Collection Process

1. **Systematic Review of Documents**: Official regulatory guidelines were retrieved from FDA, EMA, and CDSCO websites.
2. **Literature Search Strategy**: Scientific articles were identified through databases such as PubMed, Scopus, and Google Scholar using keywords: *NDA approval pathway, regulatory differences US EU India, expedited approval, data exclusivity, CTD/eCTD submissions*.
3. **Inclusion Criteria**: Documents and studies published between **2000–2025**, focusing on NDA approval frameworks, expedited pathways, and post-approval management.
4. **Exclusion Criteria**: Publications that exclusively addressed generics, biosimilars, or veterinary products unless they provided comparative regulatory insights.

Data Analysis Framework

The study employed **comparative policy analysis** using the following framework:

Legal and Institutional Mapping: Identifying the statutory basis, regulatory authorities, and organizational structures in the US, EU, and India.

Dossier Format and Submission Analysis:

Comparing CTD/eCTD implementation, regional Module 1 requirements, and electronic submission systems (FDA ESG, EMA Gateway, CDSCO SUGAM).

Procedural Timelines: Evaluating review clocks, "clock-stops," deemed approvals, and performance goal systems.

Expedited Pathways: Categorizing and comparing Fast Track, Breakthrough Therapy, PRIME, Conditional Approval, and India's accelerated mechanisms.

Exclusivity and Incentives: Analyzing data protection, orphan drug incentives, and market exclusivity policies.

Post-Approval Lifecycle Management: Examining variation frameworks, pharmacovigilance obligations, and subsequent new drug applications.

The comparative findings were organized into **thematic tables and narrative synthesis**, highlighting key regulatory divergences and convergence trends.

Validation of Findings

To ensure reliability and accuracy:

- **Triangulation** was applied by cross-verifying information from multiple sources (laws, guidance documents, peer-reviewed articles, and WHO/ICH reports).
- **Critical appraisal** of secondary literature was performed to filter out outdated or regionally biased commentary.
- **Peer comparison** of interpretation was benchmarked against published regulatory reviews by recognized experts in pharmaceutical sciences.

Ethical Considerations

As this study is based entirely on **publicly available regulatory documents and published literature**, no human or animal subjects were involved. Ethical compliance was ensured by:

- Proper citation of all sources.
- Avoidance of misrepresentation of regulatory texts.
- Use of the most updated versions of guidelines and laws at the time of analysis.

Limitations of the Methodology

- The study relies on **secondary data sources**; primary interviews with regulators or industry experts were not conducted.
- Regulatory frameworks are **dynamic**; updates during or after the study period may alter some conclusions.
- Comparative analysis may not capture **practical implementation challenges** (e.g., delays due to staffing, political context, or sponsor readiness).

Result and Discussion

Legal and institutional foundations of drug regulatory frameworks (US, EU, India)

United States (FDA) Across the US, EU, and India, the statutory bases and institutional architectures for human medicines share a common aim protect public health yet they differ in how powers are allocated and exercised. The US is highly centralized within the FDA; the EU operates a networked model that divides tasks between the EMA and national competent

authorities; India anchors authority in the Drugs & Cosmetics Act while modernizing new-drug oversight via the NDCTR 2019 under CDSCO. These design choices shape review routes, committee use, and how sponsors interact with regulators.

United States (FDA)

Statutory basis & core rules. New Drug Applications (NDAs) are governed by the FD&C Act and implemented in 21 CFR Part 314 (content, filing, review timelines, post-marketing responsibilities). Biologics are licensed under section 351 of the Public Health Service (PHS) Act with implementing regs in 21 CFR Parts 600/601 and related guidance; biologics vs. drug jurisdictional lines and exclusivity are defined under the BPCI Act framework.

Regulatory authorities & organization

FDA's Center for Drug Evaluation and Research (CDER) leads small-molecule drug evaluations; CBER leads biologics. FDA's field oversight and inspections are run by the Office of Inspections and Investigations (OII) (formerly ORA), integrating domestic and foreign inspections and import oversight. Current CDER org charts and OII restructuring confirm a single, centralized chain of command for decision-making and enforcement.

Implications:

Centralization yields clear accountability and consistent review practices; the separation of CDER/CBER with a shared field arm (OII) simplifies sponsor interfaces but demands early clarity on product classification.

European Union (EMA + Member States)

Statutory basis. The EU's "community code" for human medicines is Directive 2001/83/EC; the centralized procedure and the establishment/mandate of the European Medicines Agency (EMA) are in Regulation (EC) No 726/2004.

Regulatory authorities & organization. Scientific opinions for centralized marketing authorizations are adopted by EMA's CHMP (benefit–risk), with safety overseen by PRAC; for non-centralized routes, the CMDh coordinates mutual recognition and decentralized procedures among national competent authorities (NCAs). The Heads of Medicines Agencies (HMA) network ties EMA and NCAs into the European medicines regulatory network for work-sharing and coordination.

Implications. The network model enables capacity sharing and a single EU-wide authorization via the centralized route, but sponsors must manage interface points with both EMA committees and NCAs (especially for DCP/MRP and national tasks).

India (CDSCO / DCGI)

Statutory basis. The Drugs & Cosmetics Act, 1940 and Rules, 1945 are the foundational law; modern new-drug and clinical trial oversight is detailed in the New Drugs and Clinical Trials Rules, 2019 (NDCTR 2019).

Regulatory authorities & organization. The Central Drugs Standard Control Organization (CDSCO)—headed by the Drugs Controller General of India (DCGI)—approves new drugs, oversees clinical trials, controls imports, and coordinates with state regulators. Statutory advisory bodies, the Drugs Technical Advisory Board (DTAB) and Drugs Consultative Committee (DCC), support rule-making and harmonized enforcement across states. Implications. India blends central approval with state-level enforcement. The NDCTR 2019 has clarified processes and timelines, but sponsors still plan for state coordination post-approval.

Comparative Discussion

- Degree of centralization. FDA is unitary (single federal agency), EU is networked (EMA + NCAs via CHMP/PRAC/CMDh/HMA), and India is central-plus-state (CDSCO/DCGI with DTAB/DCC and state controllers). This affects meeting strategy, dossier routing, and inspection logistics.
- Legal clarity & procedure choice. The EU offers multiple legal routes (centralized vs. DCP/MRP), whereas the US is single-agency; India's NDCTR 2019 modernizes definitions and procedures for new drugs/CTs within the older Act/Rules framework.
- Committee governance. EMA's formalized committee system (CHMP, PRAC) is unique; FDA uses advisory committees ad hoc, while CDSCO leverages DTAB/DCC and expert committees. This influences when and how sponsors seek scientific advice and how safety is escalated EU-wide.
- Inspection & enforcement. FDA centralizes field operations in OII; EU inspections involve EMA-coordinated NCA networks; India coordinates central approvals with state enforcement—each model creates different compliance touchpoints for manufacturers.

Evaluation of Submission Formats and Dossier Requirements: The **submission format** and **dossier requirements** are critical elements of the new drug application process because they determine how data are organized, presented, and reviewed by regulatory agencies. Harmonization through the **International Council for Harmonisation (ICH)** has greatly influenced all three regions (US, EU, and India), particularly with the development of the **Common Technical Document (CTD)**. However, local adaptations persist, especially in **Module 1 (regional administrative information)** and the use of different **electronic submission platforms**.

Common Technical Document (CTD) Adoption

- **United States (FDA)**
  - **Adopted** the ICH CTD in 2003.
  - **Mandatory eCTD format** for all NDAs, ANDAs, and BLAs (since 2018).
  - Submissions are made electronically through the **FDA Electronic Submissions Gateway (ESG)**.
  - FDA provides technical specifications (Module 1: US regional info).
- **European Union (EMA/EC)**
  - **Mandatory CTD** for all Marketing Authorisation Applications (MAAs).
  - **Mandatory eCTD** since 2009 for centralised procedures; extended to MRP/DCP and national procedures.
  - Uses **EMA Gateway/WebTrader** for secure electronic transmission.
  - Module 1 tailored for EU requirements (e.g., Risk Management Plans, Pharmacovigilance System Master File).
- **India (CDSCO/DCGI)**

CTD introduced as a standard format under NDCTR 2019.

Submissions are made electronically through the **SUGAM portal** (launched 2016), but **paper submissions may still be requested** in parallel for some cases.

Module 1 contains India-specific requirements, such as Forms 44/CT-21, local clinical trial data (unless waived), and ethics committee approvals.

eCTD is **not yet mandatory**, though CDSCO has published technical guidance for phased adoption.

Electronic Submission Systems

- **FDA Electronic Submissions Gateway (ESG):** Single secure point for transmitting eCTD.
- **EMA Gateway/WebTrader:** Supports eCTD submissions, validation tools ensure compliance with EU technical requirements.
- **India's SUGAM Portal:** Online interface for submission of CTD dossiers, clinical trial applications, and variations. While it digitizes the process, system capacity and eCTD full integration are evolving.

Findings

1. **Convergence:** All three regulators require CTD-based dossiers, with Modules 2–5 essentially harmonized.
2. **Divergence:** Module 1 (regional) shows substantial variation due to administrative, legal, and pharmacovigilance requirements.
3. **Digital Evolution:** US and EU mandate eCTD for all NDAs/MAAs, while India uses SUGAM as a national platform but is transitioning towards eCTD.
4. **Implications:** Sponsors preparing global submissions must customize **Module 1** for each jurisdiction, while leveraging common Modules 2–5 for efficiency.

Comparison of review procedures and approval timelines (US, EU, India): Below I've laid out the **standard clocks**, **expedited mechanisms**, and **reliance models** used by the three regulators. I also provided three **ready-to-use tables** (open in the viewer above):

A) Standard procedures & review clocks

United States (FDA/CDER)

- Legal clocking is anchored in **PDUFA performance goals**: FDA aims to "review and act on" most **standard NDAs in 10 months** (from the 60-day filing date) and **priority NDAs in 6 months**. These goals are formalized in the current PDUFA performance document and long-standing FDA policy.

European Union (EMA/European Commission)

- In the **centralised procedure**, **CHMP** conducts the scientific assessment. **Active review time is up to 210 days**, excluding **clock-stops** granted for the applicant to answer questions. **Accelerated assessment** may reduce active time to **150 days** when justified. The **European Commission** issues the final, EU-wide decision.

India (CDSCO/DCGI)

- Under **NDCTR 2019**, CDSCO targets around **90 working days** for many new-drug permissions (import/manufacture), as reflected in official FAQs and practice notes. In 2022, the government inserted **"deemed-approval" provisions** into various NDCTR rules (via **G.S.R. 778(E)**) to reduce administrative pendency if timelines lapse. Applications are filed on SUGAM**.**

Expedited review mechanisms

United States (FDA)

- Four codified programs expedite development/review for serious conditions: **Fast Track**, **Breakthrough Therapy**, **Accelerated Approval** (surrogate endpoints with post-marketing obligations), and **Priority Review** (6-month goal). These are described in FDA guidance and patient-facing explainers.

European Union (EMA)

- Tools include **Accelerated Assessment** (150 days), **Conditional Marketing Authorisation** (approval on less-comprehensive data with obligations), **Approval under Exceptional Circumstances**, and **PRIME** (enhanced early support). EMA's procedural pages and guidance outline criteria and process.

India (CDSCO)

- **Accelerated approval** is available in life-threatening/serious diseases under NDCTR, and **clinical-trial waivers** may be granted via **Rule 101** when a drug is approved/marketed in specified **reference countries** (named by formal DCGI order). Recent SEC guidance reiterates use of Rule 101 and related waivers.

Table 1: Legal & Institutional Map (US vs EU vs India)

Dimension	United States	European Union	India
Primary statutes / core instruments	FD&C Act; 21 CFR Part 314 for NDAs; biologics under PHS Act §351 (with 21 CFR 600/601 & BPCI Act context)	Directive 2001/83/EC (community code); Regulation (EC) 726/2004 (centralized procedure; establishes EMA)	Drugs & Cosmetics Act, 1940 & Rules, 1945; NDCTR 2019 for new drugs & CTs
Lead authority	FDA (CDER for drugs; CBER for biologics)	EMA (EU level) + National Competent Authorities (NCAs)	CDSCO / DCGI (central) + State Drug Controllers
Key committees / networks	FDA Advisory Committees (as needed)	CHMP (benefit–risk), PRAC (safety), CMDh (DCP/MRP coordination), HMA network	DTAB & DCC (statutory advisory), expert committees
Field oversight / inspections	OII (FDA's unified field organization; inspections/import oversight)	NCA inspectorates within the EU network; EMA coordinates procedures & pharmacovigilance	Central–state collaboration; CDSCO HQ & zonal offices; state inspectorates
Structural characterization	Centralized single-agency model	Networked EU system (shared tasks EMA↔NCAs)	Central-plus-state model under national law

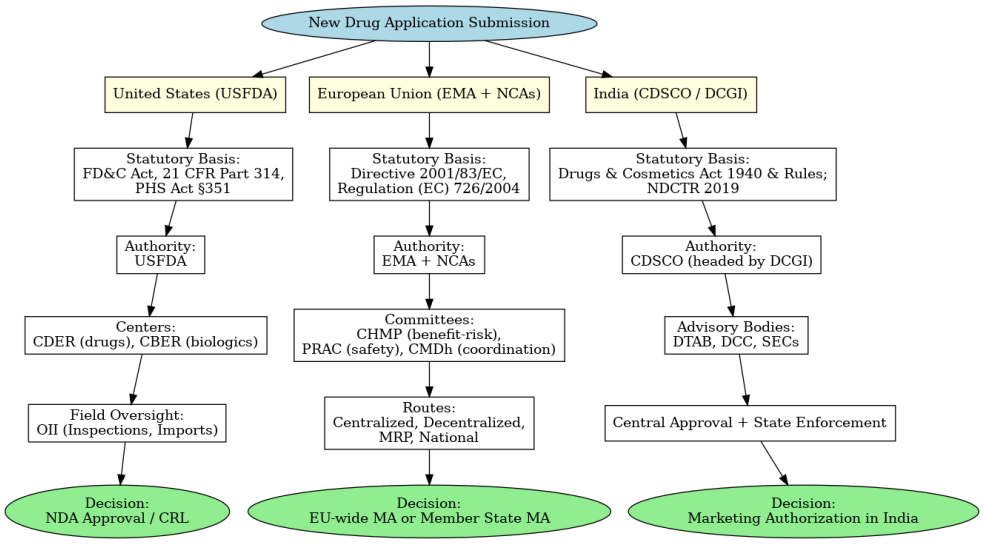
New Drug Application Submission
United States (USFDA)
European Union (EMA + NCAs)
India (CDSCO / DCGI)
Statutory Basis: FD&C Act, 21 CFR Part 314, PHS Act §351
Statutory Basis: Directive 2001/83/EC, Regulation (EC) 726/2004
Statutory Basis: Drugs & Cosmetics Act 1940 & Rules; NDCTR 2019
Authority: USFDA
Authority: EMA + NCAs
Authority: CDSCO (headed by DCGI)
Centers: CDER (drugs), CBER (biologics)
Committees: CHMP (benefit-risk), PRAC (safety), CMDh (coordination)
Advisory Bodies: DTAB, DCC, SECs
Field Oversight: OII (Inspections, Imports)
Routes: Centralized, Decentralized, MRP, National
Central Approval + State Enforcement
Decision: NDA Approval / CRL
Decision: EU-wide MA or Member State MA
Decision: Marketing Authorization in India

Fig-1: Regulatory Authorities and Approval Pathways (US vs EU vs India)

Table.2: The ICH CTD is structured into five modules

Module	Content	US (FDA)	EU (EMA)	India (CDSCO)
1	Administrative & regional info	US regional forms, labeling, REMS docs	EU application forms, RMP, PV files	Indian forms (44/CT-21), ethics approvals, import/manufacture license forms
2	Summaries (Quality, Nonclinical, Clinical)	ICH harmonized	ICH harmonized	ICH harmonized
3	Quality (CMC)	ICH harmonized; FDA-specific QbR templates	ICH harmonized; EMA QOS required	ICH harmonized; CDSCO requires local stability data
4	Nonclinical study reports	ICH harmonized	ICH harmonized	ICH harmonized
5	Clinical study reports	ICH harmonized; US IND cross-references common	ICH harmonized; GCP compliance checks	ICH harmonized; may require local Phase III bridging trial unless waived

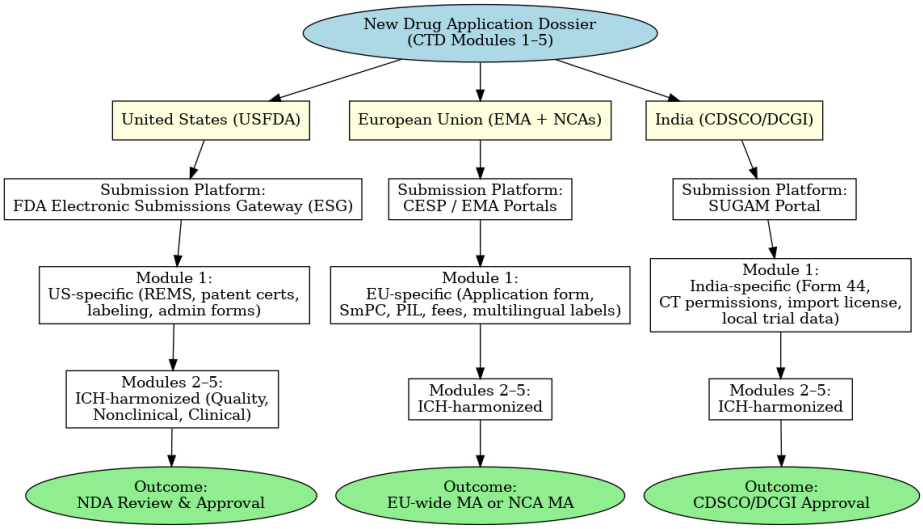
New Drug Application Dossier (CTD Modules 1–5)
United States (USFDA)
European Union (EMA + NCAs)
India (CDSCO/DCGI)
Submission Platform: FDA Electronic Submissions Gateway (ESG)
Submission Platform: CESP / EMA Portals
Submission Platform: SUGAM Portal
Module 1: US-specific (REMS, patent certs, labeling, admin forms)
Module 1: EU-specific (Application form, SmPC, PIL, fees, multilingual labels)
Module 1: India-specific (Form 44, CT permissions, import license, local trial data)
Modules 2–5: ICH-harmonized (Quality, Nonclinical, Clinical)
Modules 2–5: ICH-harmonized
Modules 2–5: ICH-harmonized
Outcome: NDA Review & Approval
Outcome: EU-wide MA or NCA MA
Outcome: CDSCO/DCGI Approval

Fig.2: Submission formats and dossier requirements (CTD/eCTD) in the US, EU, and India

Table.3: Core Review Timelines by Region

Region	Standard Review Timeline	Priority / Accelerated Timeline	Notes
United States (USFDA)	~10 months (Standard NDA Review under PDUFA goals)	~6 months (Priority Review)	Timelines are "clock-based," driven by FDA goal dates; extensions possible for major amendments.
European Union (EMA)	210 "active" days (Centralized Procedure), excluding clock-stops	150 days (Accelerated Assessment)	Decentralized/Mutual Recognition Procedures typically ~210–270 days depending on Member State coordination.
India (CDSCO/DCGI)	~12–18 months (typical) under Drugs & Cosmetics Act / NDCTR 2019	~90 days (certain accelerated review provisions under NDCTR)	Timelines improving with **SUGAM portal**; still variable depending on product class and local trial requirements.

Table.5: Expedited Pathways and Key Features

Region	Pathway(s)	Key Features	Target Timelines / Benefits
United States	- **Fast Track** - **Breakthrough Therapy** - **Priority Review** - **Accelerated Approval**	- Early interaction with FDA - Surrogate endpoints acceptable - Rolling review possible	- Priority review goal: 6 months - Accelerated approval: earlier access with confirmatory studies
European Union	- **PRIME (Priority Medicines)** - **Accelerated Assessment** - **Conditional Marketing Authorization** - **Approval under Exceptional Circumstances**	- EMA scientific advice & early engagement - Conditional approval based on less complete data if benefits outweigh risks	- Accelerated Assessment: 150 days - Conditional MA: yearly renewal until data complete
India	- **Accelerated Approval under NDCTR** - **Waiver of Local Clinical Trials for SRAs-approved drugs**	- Fast-track for drugs addressing unmet medical needs or rare diseases - Reliance on approvals from USFDA, EMA, etc.	- Decision within ~90 days for accelerated cases - Reduced requirements for local bridging trials

Table.4: Comparison of Submission Formats

Region	CTD Adoption	eCTD Requirement	Submission Portal	Special Notes
US (FDA)	Full CTD	Mandatory since 2018	FDA ESG	Module 1 = US-specific forms, REMS
EU (EMA)	Full CTD	Mandatory since 2009	EMA Gateway/WebTrader	Module 1 = EU forms, RMP, PV files
India (CDSCO)	Full CTD (NDCTR 2019)	In transition (not mandatory)	SUGAM portal	Module 1 = Indian forms, ethics approvals, local stability data

Conclusion

This thesis demonstrates that while the US, EU, and India share a common foundation in CTD-based submissions and ICH-aligned scientific standards, their regulatory approval pathways remain divergent in structure, timelines, expedited mechanisms, exclusivity protections, and post-approval oversight. The US FDA is the most centralized, structured, and resource-rich, setting global benchmarks in expedited approvals and exclusivity incentives. The EU EMA provides a unique networked model balancing scientific rigor with multi-state harmonization, supported by tools such as PRIME and Conditional MA. India's CDSCO, through NDCTR 2019, is rapidly evolving modernizing dossier requirements, introducing deemed approvals, and embracing reliance on stringent regulators while balancing affordability and access priorities. The comparative analysis highlights that regulatory science is not static but adaptive, shaped by healthcare needs, innovation pressures, and patient access imperatives. For sponsors, early integration of regulatory strategy into global development is vital to optimize filing sequences and maximize both innovation returns and public health outcomes. For regulators, greater convergence through ICH, reliance, and digital harmonization can minimize duplication, accelerate innovation uptake, and uphold safety and efficacy. Ultimately, fostering a globally convergent yet locally responsive regulatory ecosystem is essential to ensuring that life-saving medicines reach patients quickly, safely, and equitably across diverse healthcare systems.

Conflict of Interests

The authors declare no conflict of interest

Funding: This study received no specific funding from public, commercial, or not for profit funding agencies.

AI Tool Declaration

The authors declare that no AI and related tools are used to write the scientific content of this manuscript.

Data Availability

Data will be available on request

References

[1] Carpenter D. Reputation and power: Organizational image and pharmaceutical regulation at the FDA. Princeton: Princeton University Press; 2010.

[2] Abadie E, et al. Evolution of the European Medicines Agency: Achievements and future challenges. Nat Rev Drug Discov. 2017;16(10):665–6.

[3] Chaudhuri S. India's New Drugs and Clinical Trials Rules, 2019: Implications for innovation and access. J Generic Med. 2020;16(3):91–101.

[4] International Council for Harmonisation (ICH). The Common Technical Document (CTD). Geneva: ICH Secretariat; 2016.

[5] U.S. Food and Drug Administration (FDA). 21 CFR Part 314 – Applications for FDA Approval to Market a New Drug. Washington, DC: FDA; 2019.

[6] U.S. Food and Drug Administration (FDA). Prescription Drug User Fee Act (PDUFA) Performance Goals 2022–2027. Silver Spring: FDA; 2022.

[7] U.S. Food and Drug Administration (FDA). Expedited programs for serious conditions – drugs and biologics: Guidance for industry. Silver Spring: FDA; 2020.

[8] U.S. Food and Drug Administration (FDA). Biologics Price Competition and Innovation Act (BPCIA). Washington, DC: FDA; 2010.

[9] European Medicines Agency (EMA). Directive 2001/83/EC: Community code relating to medicinal products for human use. Brussels: EU; 2001.

[10] European Medicines Agency (EMA). Regulation (EC) No 726/2004: Community procedures for authorization and supervision of medicinal products. Brussels: EU; 2004.

[11] European Medicines Agency (EMA). Guideline on the Procedure for Accelerated Assessment Pursuant to Article 14(9) of Regulation (EC) No 726/2004. London: EMA; 2019.

[12] European Medicines Agency (EMA). PRIME: Priority Medicines – EMA support for early development. London: EMA; 2020.

[13] European Medicines Agency (EMA). Annual Report 2020: Digital transformation in EU regulatory network. London: EMA; 2020.
[14] Central Drugs Standard Control Organization (CDSCO). SUGAM Portal User Manual and NDCTR 2019 Guidance. New Delhi: CDSCO; 2021.
[15] Government of India. Drugs and Cosmetics Act, 1940 and Rules 1945. New Delhi: Ministry of Health and Family Welfare; 1945.
[16] Government of India. New Drugs and Clinical Trials Rules (NDCTR), 2019. New Delhi: Gazette of India; 2019.
[17] Government of India. G.S.R. 778(E): NDCTR amendment introducing deemed approvals. New Delhi: Gazette of India; 2022.
[18] Ravi R, Patel A, Shah H. Comparative evaluation of NDA and MAA pathways. Regul Aff J Pharma. 2019;30(6):12–20.
[19] Sharma P, Singh N. Regulatory reforms in India: NDCTR 2019 and implications for clinical research. Indian J Clin Res. 2020;34(2):101–8.
[20] Patel A, Shah H. Review of CDSCO reforms and impact on NDA approval timelines. J Pharm Regul Sci. 2021;12(4):45–52.
[21] Joseph A, Ramani S. Expedited pathways in global regulatory science: Comparative analysis of FDA, EMA, and CDSCO. Ther Innov Regul Sci. 2022; 56(2): 189–99.
[22] Sampath P. Data exclusivity and access to medicines in developing countries. Health Policy. 2020; 124(7):675–82.
[23] World Health Organization (WHO). Good regulatory practices: Guidelines for national regulatory authorities. Geneva: WHO; 2021.
[24] Bujar M, McAuslane N, Liberti L. Global regulatory harmonization: Opportunities and challenges for drug development. Drug Inf J. 2019; 53(1): 21–8.
[25] Hampson G. The case for regulatory reliance in emerging markets. Regul Rapporteur. 2021;18(5):22–9.
[26] Ravi R, Kumar P. Post-approval lifecycle management: Comparative analysis of US, EU, and India. J Pharm Policy Pract. 2020; 13(4): 34–42.
[27] European Commission. Variation Regulation (EC) No 1234/2008. Brussels: EC; 2008.
[28] U.S. Food and Drug Administration (FDA). Risk Evaluation and Mitigation Strategies (REMS) Guidance for Industry. Silver Spring: FDA; 2019.
[29] World Health Organization (WHO). Global benchmarking tool for evaluation of national regulatory systems. Geneva: WHO; 2018.